

D  
R2  
sulfamoyl group, or a heterocyclic <sup>radical</sup> residue; and R<sup>3</sup> represents a lower alkyl-substituted tetrazolyl group or a lower alkyl-substituted thiadiazolyl group, and the pharmaceutically acceptable non-toxic salts thereof.

REMARKS

Applicants have carefully reviewed the Official Action and are submitting this Amendment as their full and complete Response thereto. The Examiner is respectfully requested to reconsider the claims.

First, the Examiner will note that some minor corrections have been made to the specification merely to remove typographical errors and the like. The amendment to page 31 merely inserts a ratio of the three components of the solvent system which was inadvertently omitted. The Examiner will note that this conforms with what is taught on page 23, lines 9 and 10.

Claim 1 has been amended to remove several minor informalities and more clearly define the invention. An "e" has been inserted at the end of "dithietan" merely for consistency in spelling. The word "general" has been deleted as have the parentheses surrounding the definition of R<sup>4</sup>. A Markush Group of functional derivatives of a carboxyl group has been inserted to more clearly define R<sup>1</sup> and R<sup>2</sup>.

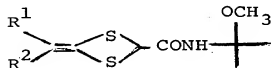
In claims 8 - 11, the definitions of the R substituents from claim 1 have been inserted and the improper reference to claim 1 in these claims has been deleted.

Turning to the Action, it is noted that the Examiner rejected all the claims under 35 USC 103 as unpatentable over Berger et al ('176) in view of Hiraoka et al and Berger et al ('090). The Examiner merely stated the conclusion that the combination of

the references renders the claims obvious. The Examiner specifically referred to "the very large disclosure in the Hiraoka et al patent" and said that Berger et al (without mentioning which Berger et al) teaches the "dithietane" type of compounds. In support of the conclusion that the combination of references renders the claims obvious, the Examiner pointed out that the claimed subject matter is in a heavily crowded art and that all the compounds possess the same utility, citing In re Woods, 199 U.S.P.Q. 317. It is presumed that the case he meant to cited was In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978). This rejection is respectfully but vigorously traversed.

It is respectfully submitted that all three of the references cited against the claims by the Examiner are irrelevant. The pertinent part of the structure of the instantly claimed compounds and those disclosed by the references are reproduced below:

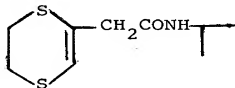
INSTANT CLAIM 1:



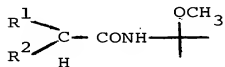
R<sup>1</sup> = carboxyl or functional derivative thereof

R<sup>2</sup> = H, alkyl, etc.

REFERENCE A - Berger et al:



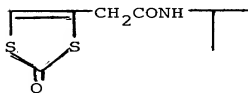
REFERENCE B - Hiraoka et al:



$R^1 = H, CN, \text{ etc.}$

$R^2 = H, CN, \text{ etc.}$

REFERENCE C - Berger et al:



By comparing these compounds, the Examiner will note two striking differences between the instantly compounds and those of the references. First, the instantly claimed compounds are dithietane carbonyls, that is, the carbonyl group is attached directly to the 4-membered dithietane ring. On the other hand, in the two Berger references, there is an acyl group wherein the carbonyl group is attached indirectly to a sulfur containing ring, the sulfur containing ring in reference A being a 6-membered ring and the sulfur ring in reference C being a 5-membered ring. In Hiraoka et al, the carbonyl group is attached to an alkyl carbon which may have substituents on it but is not part of any ring system.

The second major difference is that the instant compound is a 7-alkoxy cephalosporin whereas the compounds of both Berger et al patents are not.

Returning to the first major difference, it is pointed out that there has not been known until now any cephalosporin having a 4-membered ring carboxylic residue at the 7-position. Applicants have for the first time synthesized for the first time a new specific type of cephalosporin having a peculiar 4-membered ring structure type of carboxylic residue (the 1, 3-dithietane-2-carbonyl group) at the 7-position.

Since none of the references discloses a compound anything like this, it is submitted that they do not render the claimed compounds obvious.

The Examiner's note that the Hiraoka et al patent has a very large disclosure is noted but its significance is not understood. Perhaps the Examiner could elucidate. The Examiner's comment that Berger et al teaches the dithietane type of compounds is also noted but, as just pointed out, neither of the Berger et al patents discloses a dithietane compound. The Examiner is respectfully requested to point out specifically where, in one these references, he finds such a disclosure. As for the Examiner's citation In re Wood with the statement that the claimed subject matter is in a heavily crowded art and all of the compounds possess the same utility, Applicants wonder what the relevance of this statement and the citation may be. In In re Wood the Court was faced with a situation wherein the claimed compounds differed from the reference only by a pair of lower alkyl groups in place of a pair of hydrogen atoms. The Court held that since these compounds were so close, and possessed the same utility, one "skilled in the art" would have been "motivated" to make the claimed compounds. This is not the case here. We are here faced with a situation wherein the instantly claimed compounds are of a structure so totally different from that of any of the references that there would not be any motivation by

one of ordinary skill in the art to make the instant compounds from a consideration of the references. A dithietane ring would simply not even occur to one of ordinary skill in the art from a consideration of a 6-membered ring in one reference, and a 5-membered ring in the other reference, and no ring at all in the third reference.

The Examiner is, therefore, respectfully requested to withdraw this rejection.

Turning to the rejection of claims 8 - 10 under 35 USC 103 over the same references, it is noted that the Examiner rejected all the process claims as being conventional in the art. This rejection is respectfully traversed. The Examiner cited the case of In re Albertson, 141 U.S.P.Q. 730 (C.C.P.A. 1964) without<sup>indicating</sup> its relevance. In this case, the Court held that a method of reducing a compound with a known reducing agent to produce another compound is not patentable. But, certainly, the Examiner is aware of the more recent case of In re Mancy, 182 U.S.P.Q. 303 (C.C.P.A. 1974) wherein the Court held that a method of using an entirely new material is not obvious for the simple reason that one of ordinary skill in the art would not know of the new material. In Mancy, the end product was not novel but the starting material, a particular microorganism was. In the instantly claimed process, as embodied in claim 8 for instance, we have a process for making an entirely new compound by using an entirely new starting material. It has already been shown with reference to the product claims that the product of the process of claim 8 is new. As for the starting material, this forms the subject matter of copending application Serial No. 913,501. The claims of that application have, in substance, been allowed. Thus, claim 8, drawn to the method of using entirely new material never before known falls directly within the principles enunciated in Mancy. As for the process of

claim 9, the starting material recited there also was not in the prior art for the same reason that the reason that the final product was not. Referring to pages 7 and 8 of the specification, it will be seen that this starting material is made by the reaction of the compound denoted as "formula II" which corresponds to the starting material of claim 8 with a corresponding cephalosporin. Thus, this claim, also, falls within the principles of Mancy.

As for claim 10, Mancy also applies since the starting material, which is the subject of claim 11, is a novel starting material.

It is pointed out that while the Examiner ostensibly rejected the method claims over the cited references, it has already been irrefutably proven that the references are irrelevant and it is clear, therefore, that the claimed method involving the use of novel starting products is patentable and this cannot be negated by saying that the method steps are obvious. Mancy forbids such a rejection.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

The Examiner rejected all the claims under 35 USC 112 on the ground that a number of terms are too broad and indefinite and represent an invitation to experiment. This rejection is traversed.

One of the terms objected to by the Examiner is "carboxyl group or the functional derivative thereof". While Applicants do not believe that this term is indefinite, they have amended the claims to include the preferred functional derivatives of the carboxyl group, all of which are well-known in the art. Also, the word "general" has been deleted.

The Examiner considered "aryl", "aroyl", and "heterocyclic residue" as being too broad and indefinite. It is respectfully submitted that these terms are, in fact, neither too broad nor

indefinite. It has been repeatedly held that terms such as "alkoxy", "alkyl", "acyl", etc. "are definite" and that one skilled in the art would know what the claims cover. Ex parte Altermatt, 183 U.S.P.Q. 436 (PTO.Bd.App. 1974). The Examiner's attention is further directed to the more recent case of Ex parte Scherberich, 201 U.S.P.Q. 397 (PTO.Bd.App. 1977) where the Board, referring to the terms "aryl", "aralkyl", and "alkaryl", said "we are of the opinion that those in the art readily appreciate the total scope of the subject matter being defined....[I]t is believed apparent that the claims' use of the three terms 'aryl', 'aralkyl', and 'alkaryl' clearly indicates the intended scope of the substituent groups. As to the term 'heterocyclic' it is seen as having an art recognized meaning and appellants have placed no additional limitation on same. In considering all facets of the claimed subject matter, is our view that those working in this art would have no difficulty in ascertaining the scope of the compounds that may be employed as reactants in the claimed process." Ex parte Scherberich, 201 U.S.P.Q. at 399. Citing other well-known cases, the Board also reiterated that "it is well established that breadth alone does not constitute indefiniteness." Ex parte Scherberich, 201 U.S.P.Q. at 398. Accordingly, since the Examiner's position is so patently in error, he is requested to withdraw the rejection.

The Examiner also objected to "comprises reacting" and "comprises treating" as being too broad and indefinite. Applicants are uncertain why the Examiner considers these claims broad and indefinite. If he is objecting to the word "comprises", this is proper terminology and there is no need for Applicants to unduly limit their claims in the absence of some compelling reason such as prior art. Ex part Vollheim, 191 U.S.P.Q. 407, 408 (PTO.Bd.App. 1975). If the Examiner is objecting to "reacting" and "treating" his

attention is also directed to Volheim where the Board considered the word "treating" to be proper. Furthermore, in the Hiraoka et al patent cited by the/Examiner, and allowed by the/Examiner, the phrase "comprises contacting" and the word "contacting" are repeatedly used throughout the claims. What, it is queried, is indefinite about "reacting" or "treating" that is not indefinite about "contacting"?

As for the Examiner's gratuitous statement that the terminology he considers "is an invitation to experiment", he is reminded that it is not experimentation which is frowned upon by the law but only undue experimentation it is the Examiner's burden to prove that what is claimed would require one skilled in the art to unduly experiment. It is not Applicants' burden to prove the negative. In re Angstadt, 190 U.S.P.Q., 214, 219 (CCPA 1976).

The reference cited to show the state of the art has been considered but is not deemed pertinent.

Since all the claims are clearly in condition for allowance, and distinguish over the references of record, whether taken singly or in combination, an early notice of allowance is in order and is most earnestly solicited.

Respectfully submitted,  
BURGESS RYAN AND WAYNE

*Milton J. Wayne*  
Milton J. Wayne, Reg. 17906  
370 Lexington Avenue  
New York, New York 10017  
(212) 638-8150

MJW/H/r

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D. C. 20231, on May 23, 1979

BURGESS RYAN AND WAYNE

By: *Milton J. Wayne*

Date: May 23, 1979